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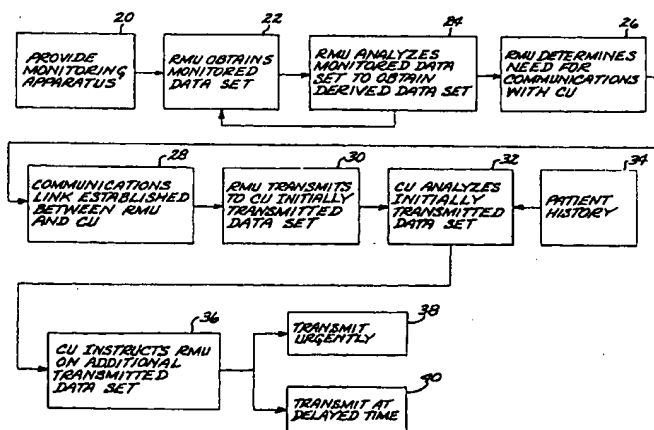
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(54) Title: DATA TRANSMISSION BETWEEN REMOTE AND CENTRAL MONITORING UNIT



(57) Abstract: A patient is monitored using a monitoring apparatus including a remote monitoring unit associated with the patient and having a sensor that measures a physiological characteristic of the patient, a central unit, and a communications device which selectively establishes a communications link between the remote monitoring unit and the central unit. The remote monitoring unit obtains a monitored data set for the patient, analyzes the monitored data set to obtain a derived data set from the monitored data set, and determines from the derived data set that communication with the central unit is required. A communications link is established with the central unit, and the remote monitoring unit transmits to the central unit an initially transmitted data set related to the monitored data set. The central unit analyzes the initially transmitted data set and instructs the remote monitoring unit as to any additional transmitted data set related to the monitored data set that is to be transmitted from the remote monitoring unit to the central unit and a time at which the additional transmitted data set is to be transmitted.

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## DATA TRANSMISSION BETWEEN REMOTE AND CENTRAL MONITORING UNIT

This invention relates to the transmission of data between a remote monitoring unit and a central unit, and more particularly to the optimization of such data transfer.

BACKGROUND OF THE INVENTION

Advances in sensor technology, electronics, and communications have made it possible for physiological characteristics of patients to be monitored even when the patients are ambulatory and not in continuous, direct contact with a hospital monitoring system. For example, US Patent 5,959,529 describes a monitoring system in which the patient carries a remote monitoring unit with associated physiological sensors. The remote monitoring unit conducts a continuous monitoring of one or more physiological characteristics of the patient according to the medical problem of the patient, an example being the heartbeat and its waveform.

Under prescribed conditions, the remote monitoring unit contacts a central unit to communicate information on the condition of the patient. For example, if the remote monitoring unit determines that the monitored physiological data suggests that the patient may be in distress or in an emergency, it may immediately and automatically transfer the monitored data to the central unit over a cellular telephone or comparable communications device. The central unit automatically, or in conjunction with medical personnel who are stationed at or are in contact with the central unit, analyzes the data and coordinates the provision of assistance to the patient when necessary. Where the analysis of the transmitted data indicates that there is no patient situation requiring immediate attention, the data is stored and may also be forwarded to the patient's physician so that treatments may be altered.

While operable, this approach may in some cases be wasteful of the battery power of the remote monitoring unit and require the expenditure of too much data transfer time over the cellular telephone system with its associated charges. The time of the medical personnel may also be used inefficiently.

There is a need for an improved approach for the control of data transfers between the remote monitoring unit and the central unit. The present invention fulfills this need, and further provides related advantages.

### SUMMARY OF THE INVENTION

5       The present invention provides an approach for monitoring a patient and providing support to the patient. The present approach adopts a new data transfer architecture with improved selectivity of data transmission but retention of the data accumulation capability to build the patient history and also the emergency capability to assist the patient on an urgent basis when needed. The battery power of the remote  
10       monitoring unit is thereby used more judiciously, the cellular telephone connect time is reduced, and medical personnel time is better managed.

      In accordance with the invention, a method of monitoring a patient comprises providing a monitoring apparatus including a remote monitoring unit associated with the patient. The remote monitoring unit includes a sensor that measures a  
15       physiological characteristic of the patient such as a cardiogram, a central unit, and a communications device which selectively establishes a communications link between the remote monitoring unit and the central unit. The remote monitoring unit obtains a monitored data set for the patient, analyzes the monitored data set to obtain a derived data set from the monitored data set, and determines from the derived data set that  
20       communication with the central unit is required. A communications link is established with the central unit, and the remote monitoring unit transmits to the central unit an initially transmitted data set related to the monitored data set. The central unit analyzes the initially transmitted data set and instructs the remote monitoring unit as to any additional transmitted data set, which may be related to the monitored data set,  
25       that is to be transmitted from the remote monitoring unit to the central unit and a time at which the additional transmitted data set is to be transmitted.

      The present invention is therefore based in an architecture where the main body of data is not automatically transmitted from the remote monitoring unit to the central unit. That approach is likely to produce unnecessarily large and unnecessarily  
30       frequent data transfers which result in depletion of the batteries of the remote

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monitoring unit and large transmission-time costs. Instead, the central unit analyzes the initially transmitted data set, which is usually a reduced data set that is derived from or determined by the monitored data set, to determine whether a more complete data transfer in the form of the additional transmitted data set is required. If so, that transmission is made at a time specified by the central unit. The time of transmission may be immediate, as when an emergency condition is sensed, or deferred, as when the additional transmitted data set is needed for the patient history. The efficiency of communication is thereby optimized while at the same time meeting the medical requirements for the patient.

10       The step of the remote monitoring unit analyzing the monitored data set may be accomplished by comparing at least one element of the derived data set to a warning limit. The analysis of the initially transmitted data set may include obtaining a patient history from a memory, and analyzing the initially transmitted data set in relation to the patient history. The central unit may instruct the remote monitoring unit  
15       to transmit the additional transmitted data set substantially immediately or at a delayed time. The additional transmitted data set and the monitored data set may be the same or may not be the same data sets.

          In one embodiment, the communications device comprises a radio frequency telephone terminal (such as a cellular or satellite telephone terminal) and a land-line  
20       telephone terminal. The radio frequency telephone connection may be made at any time, but the land-line telephone terminal is available only when the remote monitoring unit is physically connected to a land line. The transmission of the initially transmitted data set, which usually is a much smaller amount of data than the monitored data set, may be made over the radio frequency telephone connection.  
25       Upon analysis at the central unit, if there appears to be the possibility of an emergency wherein more data is needed immediately, the larger additional transmitted data set may be immediately transmitted over the radio frequency telephone connection. On the other hand, where the central unit determines that there is not an emergency but that it would be useful to have the additional transmitted data set for future reference  
30       as a part of the patient history, the central monitoring unit may instruct the remote monitoring unit to store and then transmit the additional transmitted data set at a later time over the land-line telephone terminal when such a connection is available or the

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radio frequency telephone connection when transmission costs are lower (i.e., off-peak hours).

This selective transmission approach, wherein data transmission from the remote monitoring unit is not automatic but instead is under control of the central unit, reduces the amount of data that must be transmitted over a cellular telephone connection or similar expensive communication device. This selectivity reduces cellular telephone connect time and charges to the user, and also may significantly increase the lifetime of the remote monitoring unit between battery charging, because establishing and maintaining the cell phone connection constitutes a significant portion of the battery usage of the remote monitoring unit. The human resources of the medical personnel at or in communication with the central unit are also better utilized. Only those situations that are more likely to be actual emergencies are brought to the attention of those medical personnel, so that they have more time for such potential actual emergencies.

Other features and advantages of the present invention will be apparent from the following more detailed description of the preferred embodiment, taken in conjunction with the accompanying drawings, which illustrate, by way of example, the principles of the invention. The scope of the invention is not, however, limited to this preferred embodiment.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is a block flow diagram of a method for practicing the present invention; and

Figure 2 is a simplified schematic block diagram of a preferred apparatus with which the present invention may be used.

#### DETAILED DESCRIPTION OF THE INVENTION

Figure 1 depicts an approach for practicing the present invention. A monitoring apparatus is provided, numeral 20. The monitoring apparatus may be of any operable form, and one preferred form of the monitoring apparatus 50 is illustrated in Figure 2. The monitoring apparatus 50 is shown in a simplified form

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illustrating only those portions that are required to discuss the present invention. More detail of a monitoring apparatus may be found in US Patent 5,959,529, whose disclosure is incorporated by reference.

The monitoring apparatus 50 includes a remote monitoring unit (RMU) 52  
5 carried by an ambulatory patient, and a central unit (CU) 54. The central unit 54 may be a single computer, but it is more typically a file server or a network. Other remote monitoring units, that are not "portable" in the sense that they are not carried on the person of the patient but may be at a fixed location in a patient's home or hospital facility, may be used as well. A sensor 56 measures a physiological characteristic of a  
10 patient, and is typically in contact with the patient. ("Patient" is used in a broad sense, and refers to a person being monitored.) There may be one sensor or more than one sensor 56, depending upon the parameters of the patient that are of interest. Examples of operable sensors 56 include a heart monitor sensor, a blood pressure monitor sensor, a temperature monitor sensor, a respiration sensor, a brain wave sensor, a  
15 blood chemistry sensor such as a blood glucose sensor or a blood oxygen sensor, a patient position sensor, and a patient activity sensor. Sensors of various types are known in the art, and details of their construction and operation do not form a part of the present invention.

In either event, the sensor 56 is in communication with a central processing  
20 unit (CPU) 58 of the remote monitoring unit 52, with intermediate signal conditioning equipment as necessary (not shown here). The central processing unit 58 performs analyses of the signals of the sensor 56, as will be discussed subsequently. Similarly, the central unit 54 includes a central processing unit (CPU) 60 to perform calculations and analyses, as will be discussed subsequently. (As noted, the central unit 54 and its  
25 CPU 60 may be of any operable type, such as a dedicated system, a network, or a file server. Each CPU 58 and 60 typically includes a microprocessor.)

The remote monitoring unit 52 and the central unit 54 may be placed in two-way communication with each other through a transceiver 62 located in the remote monitoring unit 52 and a communicating transceiver 64 located in the central  
30 unit 54. (The description that the transceiver is "in" the described device includes the case where the transceiver is not physically within the same structure as the CPU, but is instead in another location but in communication with the CPU. Thus, for example,

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the central unit 54 may include a file server in which the CPU 60 is located and a physically separate cellular transceiver 64 with a communication link to the file server and the CPU 60.) The transceivers 62, 64 may include any operable type of communications devices. For example, they may include a modem to establish communications over a conventional land line for routine communications. They may also include a cellular telephone transceiver to establish communications on an urgent or routine basis. The transceivers 62, 64 may also be equipped for two-way voice communication between the patient and a person at the central unit 54. The transceivers 62, 64 may interconnect over the internet, with or without land line or cellular links at each end, as well, with the internet having its own communications capabilities. The present invention is concerned in part with determining how much data should be transmitted as urgent communications and how much data should be transmitted as routine communications. The central unit 54 is provided with an interface to allow human review 66 of recommended actions of the central processing unit 60, as by the patient's physician.

Returning to the discussion of Figure 1, the remote monitoring unit 52 obtains a monitored data set for the patient using the sensor(s) 56, numeral 22. The monitored data set is often fairly voluminous, such as a continuous loop of 24 hours of a cardiograph of the patient in the form of (voltage, time) data pairs.

The remote monitoring unit 52 analyzes the monitored data set to obtain a derived data set from the monitored data set, numeral 24. The derived data set is typically much smaller in size than the monitored data set, and includes types of data that have been previously found to be significant. The derived data set may include, for example, an indication of a specified type of an abnormal heart beat (i.e., a code for the sensed abnormality), a heart rate (number of beats per minute), maximum voltage value, basic wave-shape assessment, and whether patient-specific criteria were violated by the heartbeat waveform. The derived data set is obtained from the monitored data set by conventional waveform processing procedures.

The central processing unit 58 of the remote monitoring unit 52 analyzes the derived data set, typically by comparing the values of the parameters with warning limits previously determined for the patient and provided to the remote monitoring unit 52 or by other suitable approaches. For example, if the heart rate exceeds a heart

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rate warning limit, the maximum voltage value is greater than a voltage warning limit, and/or the wave shape is not within a waveshape warning limit, the remote monitoring unit 52 may determine that there is a potential emergency with the patient or that data should be transmitted immediately for diagnostic purposes. In that event, the remote monitoring unit 52 determines that communication with the central unit 54 is required immediately, numeral 26. The remote monitoring unit 52 may instead determine that the data is of interest for inclusion in the patient's centrally stored history, but that there is no emergency at hand. In that case, the data of interest is marked for transmission at a later time, as in a daily routine transmission. The remote monitoring unit 52 may instead determine that the data is of no particular interest. In the majority of situations there is no potential emergency and communications are not required, and the monitoring apparatus then cycles from step 24 back to step 22 and repeats steps 22 and 24.

Where it has been determined that communication is required immediately, a communications link is immediately established through the transceivers 62, 64 between the remote monitoring unit 52 and the central unit 54, numeral 28. If it is not possible to establish communications through a land line, then there is an attempt to establish the more expensive and less dependable radio frequency cellular link.

The remote monitoring unit 52 transmits to the central unit 54 an initially transmitted data set, numeral 30. The initially transmitted data set may be related to the monitored data set or unrelated to the monitored data set (as for example information suggesting a sensor failure), the former being the most common. The initially transmitted data set may be the same as the derived data set, or it may include different data. For example, the initially transmitted data set may also include information from other sensors, such as a respiration rate or blood pressure of the patient. The initially transmitted data set is structured to contain the most significant information for decision making and to permit transmission to the central unit 54 in a relatively short time. The central unit 54 therefore has the most significant information needed for further decision making concisely.

The central processing unit 60 of the central unit 54 analyzes the initially transmitted data set, numeral 32. In performing this analysis, the central unit 54 often relies on patient history (numeral 34) that is stored in the central unit 54 or is



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obtainable by a further link to the doctor or hospital that is responsible for the patient. The central unit 54 may be aided in its decision making by human review and consideration of the situation, numeral 66 of Figure 2. The human review 66 may be conducted by a medical technician or by the patient's physician. However, at this stage  
5 it is preferred that the analysis step 32 be as fully automated as possible so that a decision may be made quickly regarding the need for further information. The analysis and human review at this point are not performed for the purposes of diagnosis, but instead to determine whether more information is required immediately from the remote monitoring unit 52.

10 From the information provided to it by the initially transmitted data set and from other sources such as the patient history, the central unit 54 determines the subsequent flow of information from the remote monitoring unit 52 and instructs the remote monitoring unit 52 as appropriate, numeral 36. The central unit 54 may, for example, determine that no further information need be transmitted, may determine  
15 that more information in the form of an additional transmitted data set is required on an urgent basis, or may determine that more information in the form of the additional transmitted data set is required at a later time. The volume and type of data to be transmitted is also determined. In the case where no further information is required, the communication between the remote monitoring unit 52 and the central unit 54  
20 may be immediately terminated, and the remote monitoring unit 52 cycles back to step 22. In the case where further information is required on an urgent basis, the communication link remains open and the additional transmitted data set is transmitted from the remote monitoring unit 52 to the central unit 54 immediately, numeral 38. In the case where further information is required at a later time such as at  
25 the time of routine data transmissions, the communication link is terminated as far as the urgent communication is concerned but the data of interest is marked for later transmission. At a later delayed time, such as at the time of routine data transmissions for the day, the additional transmitted data is transmitted from the remote monitoring unit 52 to the central unit, numeral 40. In a typical case, the additional transmitted  
30 information is transmitted with routine transmissions using a telephone land line, which is substantially less expensive than using a cellular telephone link and also is accomplished when the remote monitoring unit is receiving line power so that there is

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no battery drain. The additional transmitted data set selected by the central unit 54 may include the monitored data set, less than the full monitored data set, or more than the monitored data set because, for example, additional information from other sensors is required.

5       An example is helpful in illuminating the role of the central unit. If the doctor in charge of the patient has instructed that fewer than three premature ventricular contraction (PVC) events per hour is not of concern, but that three or more events per hour is of sufficient concern to require more information on an urgent basis, the remote monitoring unit 52 contacts the central unit upon the occurrence of each such  
10       event. The central unit 54 consults the patient history, which contains a running listing of the occurrence of such events. If the present event is found to be the third event in the last hour, then the central unit 54 instructs the remote monitoring unit 52 to transmit the additional transmitted data set on an urgent basis. If the present event does not result in a condition of three or more events in the last hour, it still may be  
15       desirable to transmit the waveform for the event and the adjacent time periods for the patient history but only at the next routine transmission. (Alternatively, the PVC count may be maintained by the remote monitoring unit 52, and contact established with the central unit 54 only when three PVC events are counted in any one-hour period.)

      The advantages of the present approach are illustrated in another example. By  
20       making decisions based on the initially transmitted data set, it may be necessary to maintain a cellular connection for at most a minute. On the other hand, if the entire monitored data set were automatically transmitted from the remote monitoring unit 52 to the central unit 54, the time required might be on the order of several minutes of cellular connection time to transmit each 5 minutes of the cardiogram. This  
25       connection results in a significant drain on the battery of the remote monitoring unit and extra cellular connection time and cost, which are to be avoided if possible. Where it is judged that there is an urgent need for the additional transmitted data set because the patient may be in danger or the data is of immediate diagnostic value, the cellular link is maintained and the full additional transmitted data set is communicated  
30       as necessary so that the patient may be aided.

      Although a particular embodiment of the invention has been described in detail for purposes of illustration, various modifications and enhancements may be

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made without departing from the spirit and scope of the invention. Accordingly, the invention is not to be limited except as by the appended claims.

CLAIMS

What is claimed is:

1. A method of monitoring a patient, comprising the steps of providing a monitoring apparatus including
  - a remote monitoring unit associated with the patient, the remote monitoring unit including a sensor that measures a physiological characteristic of the patient,
  - a central unit, and
  - a communications device which selectively establishes a communications link between the remote monitoring unit and the central unit;
  - the remote monitoring unit obtaining a monitored data set for the patient;
  - the remote monitoring unit analyzing the monitored data set to obtain a derived data set from the monitored data set;
  - the remote monitoring unit determining from the derived data set that communication with the central unit is required;
  - establishing a communications link with the central unit;
  - the remote monitoring unit transmitting to the central unit an initially transmitted data set related to the monitored data set;
  - the central unit analyzing the initially transmitted data set; and
  - the central unit instructing the remote monitoring unit as to any additional transmitted data set related to the monitored data set that is to be transmitted from the remote monitoring unit to the central unit and a time at which the additional transmitted data set is to be transmitted.
2. The method of claim 1, wherein the monitored data set comprises a cardiogram of the patient.
3. The method of claim 1, wherein the step of the remote monitoring unit analyzing the monitored data set includes the step of
  - comparing at least one element of the derived data set to a warning limit.

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4. The method of claim 1, wherein the step of the central unit instructing the remote monitoring unit includes the step of

the central unit instructing the remote monitoring unit to transmit the additional transmitted data set substantially immediately.

5. The method of claim 1, wherein the step of the central unit instructing the remote monitoring unit includes the step of

the central unit instructing the remote monitoring unit to transmit the additional transmitted data set at a delayed time.

6. The method of claim 1, wherein the additional transmitted data set and the monitored data set are not the same.

7. The method of claim 1, wherein the step of the central unit analyzing the initially transmitted data set includes the step of

the central unit obtaining a patient history from a memory, and analyzing the initially transmitted data set in relation to the patient history.

8. The method of claim 1, wherein the communications device comprises a radio frequency telephone terminal and a land-line telephone terminal.

9. A method of monitoring a patient, comprising the steps of providing a monitoring apparatus including

a remote monitoring unit associated with the patient,  
a central unit, and

a communications device which selectively establishes a communications link between the remote monitoring unit and the central unit;  
the remote monitoring unit obtaining a monitored data set for the patient;  
the remote monitoring unit establishing a communications link with the central unit;

the remote monitoring unit transmitting to the central unit an initially transmitted data set related to the monitored data set;

the central unit analyzing the initially transmitted data set;

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the central unit instructing the remote monitoring unit as to an additional transmitted data set that is to be transmitted from the remote monitoring unit to the central unit and a time at which the additional transmitted data set is to be transmitted; and

the remote monitoring unit transmitting the additional transmitted data set to the central unit at the time instructed by the central unit.

10. The method of claim 9, wherein at least a part of the additional transmitted data set is related to the monitored data set.

11. The method of claim 9, wherein the monitored data set comprises a cardiogram of the patient.

12. The method of claim 9, wherein the step of the central unit instructing the remote monitoring unit includes the step of

the central unit instructing the remote monitoring unit to transmit the additional transmitted data set substantially immediately.

13. The method of claim 9, wherein the step of the central unit instructing the remote monitoring unit includes the step of

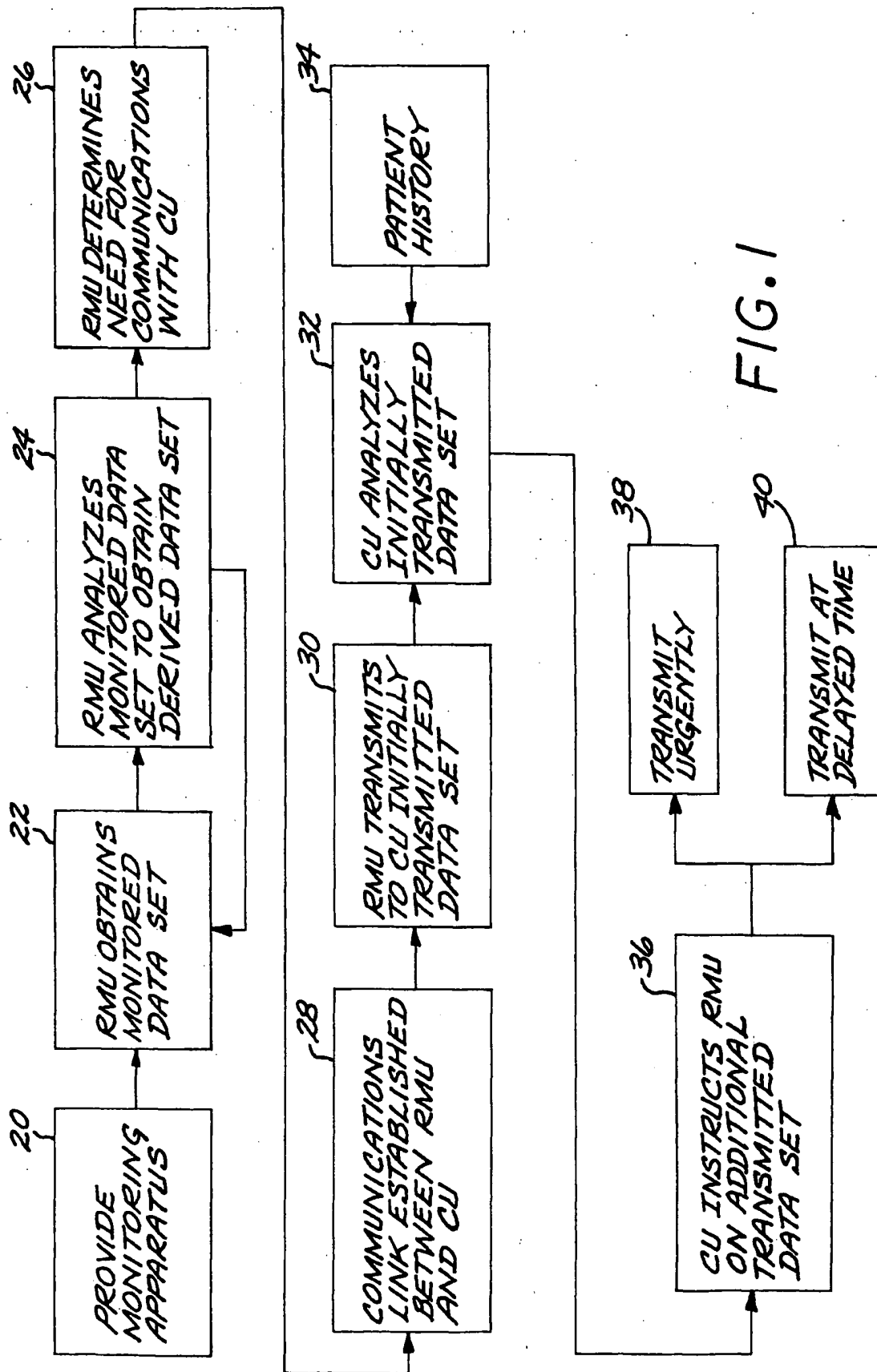
the central unit instructing the remote monitoring unit to transmit the additional transmitted data set at a delayed time.

14. The method of claim 9, wherein the additional transmitted data set and monitored data set are not the same.

15. The method of claim 9, wherein the step of the central unit analyzing the initially transmitted data set includes the step of

the central unit obtaining a patient history from a memory, and

the central unit analyzing the initially transmitted data set in relation to the patient history.



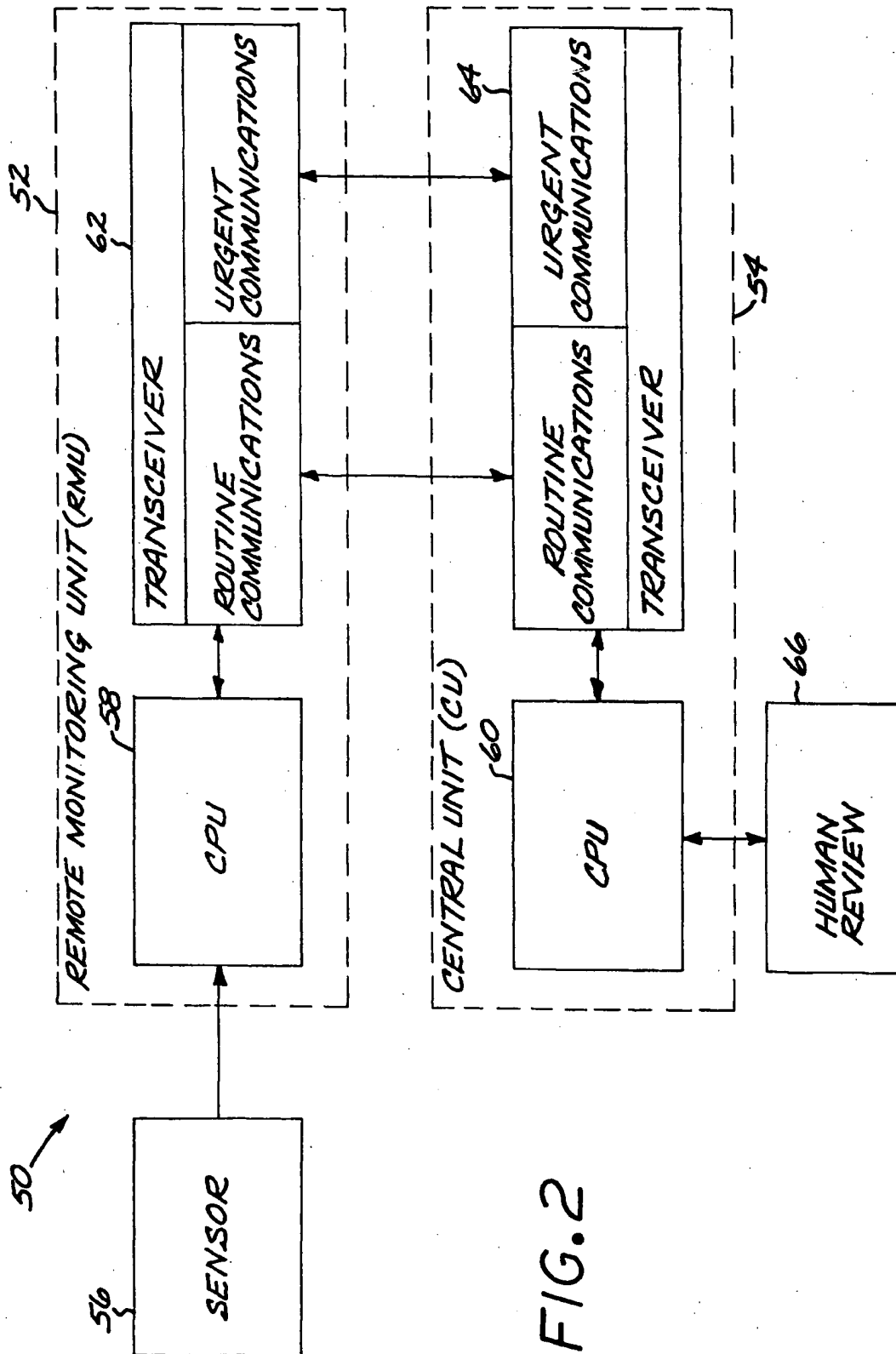


FIG.2



# INTERNATIONAL SEARCH REPORT

International Application No  
PCT/US 02/12875

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61B5/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the International search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 44 41 907 A (HEWLETT PACKARD CO) 22 June 1995 (1995-06-22) column 5, line 19 - line 39 column 9, line 24 - column 11, line 25 ----	
A	US 5 544 661 A (LONG PAUL V ET AL) 13 August 1996 (1996-08-13) column 2, line 57 - column 4, line 10 -----	

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents :

\*A\* document defining the general state of the art which is not considered to be of particular relevance

\*E\* earlier document but published on or after the international filing date

\*L\* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

\*O\* document referring to an oral disclosure, use, exhibition or other means

\*P\* document published prior to the international filing date but later than the priority date claimed

\*T\* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

\*X\* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

\*Y\* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

\*A\* document member of the same patent family

Date of the actual completion of the international search

2 August 2002

Date of mailing of the international search report

21/08/2002

Name and mailing address of the ISA

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Fax (+31-70) 340-3016

Authorized officer

Martelli, L

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.1

Although claims 1 to 15 are directed to a diagnostic method practised on the human/animal body, the search has been carried out and based on an apparatus performing the claimed methods.

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Continuation of Box I.1

Claims Nos.: 1-15

Rule 39.1(iv). PCT - Diagnostic method practised on the human or animal body

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US 02/12875

## Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 1-15  
because they relate to subject matter not required to be searched by this Authority, namely:  
see FURTHER INFORMATION sheet PCT/ISA/210
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

### Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No  
PCT/US 02/12875

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
DE 4441907	A	22-06-1995	DE 4441907 A1	22-06-1995
			GB 2285135 A	28-06-1995
			JP 7234982 A	05-09-1995
<hr/>				
US 5544661	A	13-08-1996	NONE	
<hr/>				